REMARKS

In response to the office action mailed April 27, 2004, applicants submit this Supplemental Amendment and Withdrawal of Request for Interference. Applicants have canceled claims 1-19 herein and have amended claims 20, 21, 23, 24, 26, and 27. Applicants have also added new claims 28-31.

As discussed with the examiner, this Supplemental Amendment replaces the Amendment dated August 27, 2004 and the Response to Notice of Non-compliant Amendment dated December 10, 2004. Reconsideration of the application is respectfully requested.

Withdrawal of Request for Interference

Applicants hereby withdraws the Request for Interference Under 37 C.F.R. §1.607(a) dated February 28, 2003. Applicants have canceled claims 16-19, which were copied from U.S. Patent No. 6,293,951 (the '951 patent) to Alferness. The instant application does not include any pending claims that claim the same subject matter as the claims of the '951 patent. Accordingly, no basis for interference between the instant application and the '951 patent exists.

Objections to Claims 21 and 24

In the office action, the examiner objected to claims 21 ands 24. The examiner asserted that the limitation of "outer diameter of 0.349 inches" is not commensurate in scope with the specification and suggested inserting –approximately-- before "0.349" in both claims 21 and 24. Applicants have amended claims 21 and 24 pursuant to the examiner's suggestion. Applicants respectfully submit that the objection to claims 21 and 24 should be withdrawn.

Claim Rejection Under 35 U.S.C. 101

The examiner rejected claim 26 under 35 U.S.C. 101 as allegedly being directed to non-statutory subject matter. The examiner asserted that claim 26 is improper because the outer surface is claimed as sealing with an interior of a body passageway.

Pursuant to the examiner's suggestion, applicants have amended claim 26 to change "seals" with --is configured to seal--. Applicants respectfully submit that the rejection under 35 U.S.C. 101 has been overcome.

Claim Rejections under 35 U.S.C. 103

The examiner rejected claims 16-27 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,957,949 to Leonhardt in view of U.S. Patent No. 5,411,552 to Andersen.

Claims 16-19

The rejection of claims 16-19 is rendered moot, as claims 16-19 are canceled from the instant application.

Claims 20-27

Independent claims 20, 23, 26, and 27 all include the limitation of a frame coupled to the valve, wherein the frame self-expands within a pulmonic passageway sufficiently to anchor the flow control device within the pulmonic passageway. Leonhardt and Andersen, both alone and in combination, fail to teach or suggest such a feature.

Leonhardt describes a valve stent 20 comprised of three elements, including a stent 26, a biological valve 22, and graft material 24. Leonhardt's stent 26 is self-expanding. See Leonhardt, col. 5, line 47. However, when the valve stent 20 is deployed in a body passageway, the stent 26 does not self-expand sufficiently to anchor the valve stent 20 in the passageway. Rather, Leonhardt requires that an expansion balloon 154 be used to anchor the valve stent in the body passageway. As stated in Leonhardt, after the valve stent is positioned in the body passageway, "[e]xpansion balloon 154 is then inflated to a pressure sufficient to hold the distal end of valve stent 20 secure against the living tissue as seen in FIG. 9C. This ensures proper placement is maintained during the remainder of the deployment procedure and allows valve stent to mold itself quickly into the living tissue at the placement site and achieve a patent

seal." (See Leonhardt, col. 11, lines 3-9.) Leonhardt provides no teaching or suggestion of a device that self-expands sufficiently to anchor in a body passageway.

Indeed, Leonardt teaches that the device is provided with a light-activated bioadhesive that is used to bind the Leonhardt device in place in a body passageway. The bioadhesive is directly located on the outside of the graft material or contained in photosensitive packets on the graft material. The adhesive is activated or released by exposing it to light of a proper frequency. As described in Leonhardt, after the device is placed in a body passageway using the expansion balloons, a "light emitting catheter capable of emitting light at the proper frequency to activate tissue bioadhesive 56 or packets 62 containing tissue bioadhesive 56 is inserted and energized. Bioadhesive 56 is exposed to the light sufficient to activate it ...."

Furthermore, Leonhardt et al. actually teaches away from using a frame that self-expands. Leonhardt openly states that self-expanding stents would not comply with the natural movement of the cardiovascular system (see col. 2, lines 64-66). That is apparently why Leonhardt et al. uses an expansion balloon 154 to seal the graft material 24 of the valve 20 to the wall of the biological passageway, because self-expanding stents would purportedly not work. See, for example, col. 2, lines 23-26, where Leonhardt et al. explains that cooled Nitenol, which is a self-expanding metal alloy, "does not exhibit sufficient force upon warming and reformation of its intended shape to maintain a seal between the stent and the tissue." So according to Leonhardt, self-expanding stents are not only too stiff to conform to the constant motion to which they would be exposed, but they do not exhibit enough force against biological passageways to maintain a seal between the stent and tissue. Thus, Leonhardt teaches away from using self-expanding stents or frames to seal against biological passageways, and one of ordinary skill in the art would not have been led by Leonhardt et al. to use self-expanding stents or frames to seal against biological passageways.

Andersen also fails to teach or suggest a flow control device that self-expands sufficiently to anchor in a body passageway. Andersen describes a valve prosthesis for

implantation in the body. Unlike the method recited in claim 25, deployment of the Andersen valve prosthesis requires the use of an expansion balloon 13 to expand the prosthesis sufficient to anchor the prosthesis in a body passageway. (See Andersen, col. 6, lines 20-44, FIGS. 5-7.) Although Andersen describes an embodiment of the valve prosthesis that self-expands (see col. 7, lines 17-23), Andersen makes no mention of the valve prosthesis self-expanding sufficiently to anchor in the body passageway.

In view of the foregoing, applicants respectfully submit that the rejection of claims 20, 23, 26, and 27 under 35 U.S.C. §103(a) should be withdrawn. Claims 21-22 and 24-45 depend from claim 20 and 23, respectively, and all of these claims recite subject matter that is neither taught nor suggested by the cited art. In addition, these claims are patentable in view of their dependence on claims 20 and 23.

New Claims

New claims 28 and 30 recite that the valve is movable between an open configuration allowing fluid flow through the valve and a closed configuration restricting fluid flow through the valve, the valve being biased into the closed configuration. Applicant submits that none of the cited references show a valve that is biased into a closed configuration.

Claims 29 and 31 recite that the device or valve is configured for placement in a bronchial passageway of a lung, wherein the device or the valve has a construction that blocks air flow through the bronchial passageway when the valve is in the closed configuration. Applicant submits that none of the devices in cited references have a construction that blocks air flow through a bronchial passageway.

The Leonhardt valve stent has a construction that is completely unsuited for blocking airflow through a bronchial passageway, as the construction of the Leonhardt device provides several air leak paths that would prevent the device from blocking air flow. For example, the graft material 24 is a low-porosity woven fabric (Leonhardt col. 5, lines 53-54). Thus, the graft material that surrounds the Leonhardt valve stent is

porous, which provides a source of leak paths. Although Leonhardt states that the graft material has a "low" porosity, any porosity at all will result in air leakage across the device if placed in a bronchial passageway.

Moreover, the Leonhardt valve stent includes sutures that are stitched between the graft and the frame to secure the graft to the frame. (Leonhardt col. 6, lines 25-27.) The graft material 24 is attached to the stent 26 by sewing the graft material 24 to the stent 26 using polyester suture. (Leonhardt col. 5, lines 36-37; col. 5 lines 62- col. 6, line 8.) Such suture stitches create holes in the graft that form additional leak paths through which air can flow across the device.

Furthermore, Leonhardt teaches that the graft material is a "woven fabric". By definition, a woven fabric is formed of interweaved threads. Thus, a woven fabric inherently includes holes between the thread weaves in the fabric, which would result in additional leak paths across the device if it were placed in a bronchial passageway.

Such leak paths would provide a passageway for air to flow across the Leonhardt device if it were positioned in a bronchial passageway. Moreover, there is no suggestion or motivation to change the Leonhardt valve to overcome its deficiencies with respect to blockage of airflow in a bronchial passageway. Leonhardt makes no mention at all of being used in a lung environment and makes no suggestion of materials or construction that would motivate one of skill in the art to use the device in a lung environment.

Double Patenting Rejections

The examiner rejected claims 16-22 and 26 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,954,766 in view of Andersen and over claims 1 and 7 of U.S. Patent No. 6,632,243 in view of Andersen. The double patenting rejection of claims 16-19 is rendered moot due to the cancellation of claims 16-19.

Claim 20 recites a one-way valve dimensioned for pulmonary placement, wherein the valve is configured to restrict fluid flow and a frame coupled to the valve, wherein

the frame self-expands within a pulmonic passageway sufficiently to anchor the flow control device within the pulmonic passageway. Neither the combination of claim 1 of U.S. Patent No. 5,954,766 with Andersen nor claims 1 and 7 of U.S. Patent No. 6,632,243 with Andersen results in all of the limitations of claim 20. Consequently, the double patenting rejection of claim 20 and its dependent claims should be withdrawn.

Claim 26 recites a one-way valve dimensioned for pulmonary placement, wherein the valve is configured to restrict fluid flow and wherein an outer surface of the device seals is configured to seal with an interior of a body passageway; and a frame coupled to the valve, wherein the frame self-expands within a pulmonic passageway sufficiently to anchor the flow control device within the pulmonic passageway. Neither the combination of claim 1 of U.S. Patent No. 5,954,766 with Andersen nor claims 1 and 7 of U.S. Patent No. 6,632,243 with Andersen results in all of the limitations of claim 26. Consequently, the double patenting rejection of claim 26 should be withdrawn.

Applicants respectfully submit that all claims should be found patentable to the applicants, and an interference should be declared with U.S. Patent No. 6,293,951. If the Examiner has any questions regarding the foregoing, she is cordially invited to contact the undersigned so that any such matters may be promptly resolved.

Respectfully submitted,

Date: February 24, 2005

Fred C. Hernandez
Reg. No. 41,832

PTO Customer No. 20985
Fish & Richardson P.C.
12390 El Camino Real
San Diego, California 92130
Telephone: (858) 678-5625
Facsimile: (202) 626-7796
Email: fhernandez@fr.com

10487734.doc